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| 10/774,820 | 02/09/2004 | Cameron W. Tanner | SP00-391C | 9241 |
| 22928 | 7590 | 09/29/2006 | EXAMINER | |
| CORNING INCORPORATED | | | FORMAN, BETTY J | |
| SP-TI-3-1 | | | ART UNIT | PAPER NUMBER |
| CORNING, NY 14831 | | | 1634 | |

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,820

Applicant(s)

TANNER ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

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DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, application 09/650,885 upon which priority is claimed does not provide adequate support under 35 U.S.C. 112 for claims 1-37 of this application.

The instant claims are drawn to a layer of individual particles of an organic material wherein the particles have a mean pore size of not less than about $0.1\mu\text{m}$ and forming a network of inorganic material from the particles to form a plurality of interconnecting voids of a predetermined mean size of not less than about $0.1\mu\text{m}$.

The applications upon which priority is claimed do not provide support for these limitations. While the '885 application teaches a "mean particle size of $3\text{-}5\mu\text{m}$ " (page 12, lines 10-11) and pore size of $40\text{-}50\text{ \AA}$ and $0.1\text{-}20\mu\text{m}$ (page 5, lines 23-30 and page 8, line 1), the applications do not teach or describe the range as instantly claimed.

Because the '885 application does not provide adequate support under 35 U.S.C. 112 for claims 1-37 of this application, the effective filing date for the instant claims is the filing date of application 10/101,135 i.e. 18 March 2002.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1- 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-21 are indefinite in Claim 1 and Claims 13, 31 and 37 are each indefinite for the recitations "not less than about" and/or "at least about".

It is vague and indefinite what is meant by the phrases "not less than about" and "at least about". The phrases "not less than" and "at least" typically indicate a minimum point. The phrases in the instant claims however, are contraverted by the term "about" which implies that values above and below the minimum point are permitted. Therefore, it is also unclear if "about 0.1" simply includes .01 or if it also includes 0.9-0.7 as well. In Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (CAFC 1991), the CAFC stated, "The district court held claims 4 and 6 of the patent invalid because their specific activity limitation of "at least about 160,000" was indefinite". After review, the CAFC states "We therefore affirm the district court's determination on this issue." Thus, the CAFC found the phrase "at least about" indefinite where the metes and bounds of the term were not defined in the specification.

Claim 8 is indefinite for the recitation "said interlayer" because the recitation lacks proper antecedent basis in Claim 1. It is suggested the claim be amended to provide proper antecedent basis e.g. amend Claim 8 to depend from Claim 7.

Claims 22-37 are indefinite in Claim 22 for the recitation "said contiguous inorganic material" because both "contiguous" and "material" lack proper antecedent basis in the claim. It is suggested the claim be amended to provide proper antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6, 9-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Glazer et al (WO 00/61282, published 19 October 2000) as defined by Giancoli, D. C. (Physics: Principles with Applications, Prentice Hall, NJ, 1991, page 591).

Regarding Claim 1, Glazer et al disclose a substrate for attaching analytes, the substrate comprising a porous predominately inorganic layer derived from a frit of particles adhered to a flat, rigid non-porous, inorganic understructure (glass microscope slide), the inorganic layer having a plurality of interconnected voids that extend through to a top surface of the porous inorganic layer (Fig. 2, pores #128, page 17, second paragraph and page 50, lines 2-4), the voids having a predetermined mean size of not less than about 0.1µm dispersed throughout the layer (page 11, lines 18-20), and preparing the top surface for binding biological or chemical analytes (Example 1, pages 34-37). It is noted that the instant specification defines frit layer of individual particles as glass particles e.g. borosilicate (¶ 48 and 56). Glazer et al define the particle layer as borosilicate particles (page 16-17 and Fig. 1-2). Glazer et al further teach the voids are “open” and/or filed with gas (page 15, lines 25-29 and page 50, lines 2-4). Giancoli defines the index of refraction for air is 1.0 and for glass is 1.46-1.58 (page 591). Hence, air in the voids and the glass particles provide a high contrast in indices of refraction as required by the instant claims.

Regarding Claim 2, Glazer et al disclose the substrate further comprises a uniform coating of a binding agent (e.g. silanes) over at least part of the surface area (page 19, line 10- page 21, line 23).

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Regarding Claims 3-4, Glazer et al disclose the substrate wherein the binding agent is a cationic polymer i.e. aminopropyltriethoxysilane (page 11, lines 11-15).

Regarding Claim 6, Glazer et al disclose the substrate wherein the porous inorganic layer forms a networked matrix (page 8, lines 11-13).

Regarding Claims 9-11, Glazer et al disclose the substrate wherein the inorganic material is glass or metal oxide i.e. silicate, aluminosilicate, boroaluminosilicate or borosilicate glass (page 8, line 24-page 9, line 9; page 17, lines 1-17; and page 18, lines 1-24).

Regarding Claim 12, Glazer et al disclose the substrate wherein the material is selected from TiO_2 , SiO_2 , AlO_2 , CrO_2 , CuO_2 , ZnO_2 , ZrO_2 (page 18, lines 8-14).

Regarding Claim 13, Glazer et al disclose the substrate wherein the inorganic layer has a thickness of at least about $5\mu\text{m}$ (page 2, lines 16-19)

Regarding Claims 14-15, Glazer et al disclose the substrate wherein the network is formed by adhesion of particles having a mean size of about $0.5\mu\text{m}$ to about $3.5\mu\text{m}$ (page 3, lines 13-15 and page 36, lines 7-10).

Regarding Claims 16-17, Glazer et al disclose the substrate wherein the voids have a mean size of about 0.5 to $3.5\mu\text{m}$ (page 11, lines 18-20).

Regarding Claim 18, Glazer et al disclose the substrate wherein the voids consist of either a gas or liquid i.e. the pores are infused with a gas or liquid (page 15, lines 25-29).

Regarding Claim 19, Glazer et al disclose the understructure is glass (page 8, lines 19-20).

Regarding Claim 20, Glazer et al disclose the substrates provide a sensitivity of at least one order of magnitude greater than comparable non-porous substrates (page 40, lines 15-17 and page 55, lines 17-21).

Regarding Claim 21, Glazer et al disclose the substrate wherein the porous inorganic layer is derived from at least partial sintering (page 17, lines 8-17).

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Claim Rejections - 35 USC § 102/103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 5, 22-25 and 27-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Glazer et al (WO 00/61282, published 19 October 2000).

Regarding Claim 5, Glazer et al disclose a substrate for attaching analytes, the substrate comprising a porous predominately inorganic layer derived from a frit of particles adhered to a flat, rigid non-porous, inorganic understructure (glass microscope slide), the inorganic layer having a plurality of interconnected voids that extend through to a top surface of the porous inorganic layer (Fig. 2, pores #128, page 17, second paragraph and page 50, lines 2-4), the voids having a predetermined mean size of not less than about 0.1µm dispersed throughout the layer (page 11, lines 18-20), wherein the inorganic material and contents of the voids to exhibit a high contrast in their indices of refraction relative to each other and preparing the top surface for binding biological or chemical analytes (Example 1, pages 34-37). It is noted that the instant specification defines frit layer of individual particles as glass particles e.g. borosilicate (¶ 48 and 56).

Glazer et al define the support as borosilicate glass (page 8, lines 19-20) and the particle layer as borosilicate particles (page 16-17 and Fig. 1-2). Glazer et al further teach the substrate is "templated" whereby the polymer between the particles is removed using appropriate temperatures e.g. glass transition temperature (page 9, lines 10-18), thus leaving interconnected particles (e.g. borosilicate glass) on the substrate (e.g. borosilicate glass).

Glazer et al also teach exposures of the substrates to stringent hybridization conditions using

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long incubations and high temperatures whereby the substrate provides improved results when compared to other glass substrates (page 42, lines 21-25). This clearly illustrates that the understructure and porous layer are thermally compatible.

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Glazer et al is silent with regard to the compatibility of the coefficient of thermal expansion. However, the compatibility recited in Claims 5 and 22 is deemed to be inherent in borosilicate particles and substrates of Glazier because one of ordinary skill in the art would have expected the same substance (i.e. borosilicate) to have compatible, if not identical coefficient of thermal expansion. Furthermore, the improved hybridization signals in Glazer et al clearly illustrate thermal compatibility because absent thermal compatibility, the substrate would not provide the 15 to 45 fold improved signal high temperatures.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate composition of Glazer et al to provide thermal compatibility. One of ordinary skill in the art would have been motivated to do so for the obvious benefit of maintaining structural integrity under stringent assay conditions as desired in the art (Glazer et al, page 42, lines 21-25).

The burden is on applicant to show that the claimed compatibility is either different or non-obvious over that of Glazer et al.

Regarding Claim 22, Glazer et al disclose a planar substrate for attaching analytes, the substrate comprising a porous predominately inorganic layer derived from a frit of particles adhered to a flat, rigid non-porous, inorganic understructure (glass microscope slide), the inorganic layer having a plurality of interconnected voids that extend through to a top surface of the porous inorganic layer (Fig. 2, pores #128, page 17, second paragraph and page 50, lines 2-4), the voids having a predetermined mean size of not less than about 0.1 μ m dispersed throughout the layer (page 11, lines 18-20), wherein the inorganic material and contents of the voids to exhibit a high contrast in their indices of refraction relative to each other and

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preparing the top surface for binding biological or chemical analytes (Example 1, pages 34-37) wherein the substrate further comprises a uniform coating of a binding agent (e.g. silanes) over at least part of the surface area (page 19, line 10-page 21, line 23). It is noted that the instant specification defines frit layer of individual particles as glass particles e.g. borosilicate (§ 48 and 56).

Glazer et al define the support as borosilicate glass (page 8, lines 19-20) and the particle layer as borosilicate particles (page 16-17 and Fig. 1-2). Glazer et al further teach the substrate is "templated" whereby the polymer between the particles is removed using appropriate temperatures e.g. glass transition temperature (page 9, lines 10-18), thus leaving interconnected particles (e.g. borosilicate glass) on the substrate (e.g. borosilicate glass). Glazer et al also teach exposures of the substrates to stringent hybridization conditions using long incubations and high temperatures whereby the substrate provides improved results when compared to other glass substrates (page 42, lines 21-25). This clearly illustrates that the understructure and porous layer are thermally compatible.

The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Glazer et al is silent with regard to the compatibility of the coefficient of thermal expansion. However, the compatibility recited in Claims 5 and 22 is deemed to be inherent in borosilicate particles and substrates of Glazier because one of ordinary skill in the art would have expected the same substance (i.e. borosilicate) to have compatible, if not identical coefficient of thermal expansion. Furthermore, the improved hybridization signals in Glazer et al clearly illustrate thermal compatibility because absent thermal compatibility, the substrate would not provide the 15 to 45 fold improved signal high temperatures.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate composition of Glazer et al to provide thermal compatibility. One of ordinary skill in the art would have been motivated to

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do so for the obvious benefit of maintaining structural integrity under stringent assay conditions as desired in the art (Glazer et al, page 42, lines 21-25).

The burden is on applicant to show that the claimed compatibility is either different or non-obvious over that of Glazer et al.

Regarding Claim 23, Glazer et al disclose the substrates provide a sensitivity of at least one order of magnitude greater than comparable non-porous substrates (page 40, lines 15-17).

Regarding Claims 24-25, Glazer et al disclose the substrate wherein the binding agent is a cationic polymer i.e. aminopropyltriethoxysilane (page 11, lines 11-15).

Regarding Claims 27-29, Glazer et al disclose the substrate wherein the inorganic material is glass or metal oxide i.e. silicate, aluminosilicate, boroaluminosilicate or borosilicate glass (page 8, line 24-page 9, line 9; page 17, lines 1-17; and page 18, lines 1-24).

Regarding Claim 30, Glazer et al disclose the substrate wherein the material is selected from TiO_2 , SiO_2 , AlO_2 , CrO_2 , CuO_2 , ZnO_2 , ZrO_2 (page 18, lines 8-14).

Regarding Claim 31, Glazer et al disclose the substrate wherein the inorganic layer has a thickness of at least about $5\mu\text{m}$ (page 2, lines 16-19)

Regarding Claims 32-33, Glazer et al disclose the substrate wherein the particles having a mean size of about $0.5\mu\text{m}$ to about $3.5\mu\text{m}$ (page 3, lines 13-15 and page 36, lines 7-10).

Regarding Claims 34-35, Glazer et al disclose the substrate wherein the voids have mean size of about 0.5 to $3.5\mu\text{m}$ (page 11, lines 18-20).

Regarding Claim 36, Glazer et al disclose the substrate wherein the voids consist of either a gas or liquid i.e. the pores are infused with a gas or liquid (page 15, lines 25-29, page 17, lines 23-25 and page 50, lines 2-4).

Regarding Claim 37, Glazer et al disclose the substrate wherein the voids are defined by a networked matrix (page 8, lines 11-13), the network of inorganic material having a

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predetermined mean size of not less than about 0.1 μ m dispersed throughout the layer (page 11, lines 18-20).

Claim Rejections - 35 USC § 103

9. Claims 7-8 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glazer et al (WO 00/61282, published 19 October 2000) as defined by Giancoli, D. C. (Physics: Principles with Applications, Prentice Hall, NJ, 1991, page 591) as applied to Claims 1 and 22 above and further in view of Nagasawa et al (U.S. Patent No. 6,897,021, filed 20 March 2001).

Regarding Claims 7-8 and 26, Glazer et al disclose a substrate for attaching analytes, the substrate comprising a porous predominately inorganic layer derived from a frit of particles adhered to a flat, rigid non-porous, inorganic understructure (glass microscope slide), the inorganic layer having a plurality of interconnected voids that extend through to a top surface of the porous inorganic layer (Fig. 2, pores #128, page 17, second paragraph and page 50, lines 2-4), the voids having a predetermined mean size of not less than about 0.1 μ m dispersed throughout the layer (page 11, lines 18-20), and preparing the top surface for binding biological or chemical analytes (Example 1, pages 34-37). It is noted that the instant specification defines frit layer of individual particles as glass particles e.g. borosilicate (§ 48 and 56).

Glazer et al is silent regarding an intermediate layer between the porous layer and non-porous understructure. However, Nagasawa teach a similar substrate comprising a porous layer over a non-porous structure and further comprising an intermediate layer whereby the porous carrier is orderly arranged (Column 3, lines 48-55, Figure 5 and Example 6). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate of Glazer et al by using an intermediate layer as taught by Nagasawa. One of ordinary skill in the art would have been motivated to do so for the

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expected benefit of obtaining an orderly arrangement on the substrate as desired in the art (Nagasawa et al, Column 3, lines 48-55, Figure 5 and Example 6).

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate composition of Glazer et al and Nagasawa to provide thermal compatibility between the substrate, porous layer and intermediate layer. One of ordinary skill in the art would have been motivated to do so for the obvious benefit of maintaining structural integrity under stringent assay conditions as desired in the art (Glazer et al, page 42, lines 21-25).

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

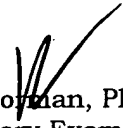
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 26, 2006